K071236

510(k) SUMMARY

Submitted by:

Kim B. Kracke

Assistant Director, Regulatory Affairs

Alcon, Inc.

6201 South Freeway

Fort Worth, Texas 76134-2099

(817) 551-8338 (Phone)

(817) 551-4630 (Fax)

Device Name:

Proprietary Name: ALCON® Multi-Purpose Solution

Common Name: Soft (hydrophilic) Contact Lens Care Solution

Classification Name: Under 21 CFR §886.5928 titled Soft (hydrophilic) contact lens care products, this solution is classified as a Class II – Special Controls Product.

Indications for Use:

For use in the daily cleaning, conditioning, rinsing, chemical (not heat) disinfection, and storage of silicone hydrogel contact lenses as recommended by your eye care practitioner.

Description:

ALCON® Multi-Purpose Solution is a sterile, buffered, isotonic, aqueous solution containing sodium chloride, sodium borate, propylene glycol, sorbitol, edetate disodium, TETRONIC® 1304, hydroxypropyl guar and POLYQUAD® (polyquaternium-1) 0.00025% preservative.

TETRONIC® is a trademark of BASF.

Substantial Equivalence:

ALCON® Multi-Purpose Solution is substantially equivalent in terms of its actions and indications for use to ALCON® Opti-Free® RepleniSH® Multi-Purpose Disinfecting Solution and ALCON® Unique-pH® Multi-Purpose Solution.

Safety and Effectiveness:

Cleaning Studies:

ALCON® Multi-Purpose Solution is an isotonic aqueous solution which contains a surface active agent, TETRONIC® 1304. The cleaning efficacy of the solution has been evaluated through the determination of the Critical Micelle Concentration (CMC). The TETRONIC® 1304 concentration is well above the CMC, which ensures the effective cleaning function of the product. These findings are supported by results of clinical evaluations.

Compatibility Studies:

Lens compatibility studies performed show that ALCON® Multi-Purpose Solution is compatible with silicone hydrogel lenses.

Microbiology Studies:

A series of studies based on EN ISO 14729:2001 Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses, the ANSI Contact Lens Care Products Standard and EN ISO 14730:2000 Ophthalmic optics- Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date were completed to demonstrate the microbiological efficacy of ALCON® Multi-Purpose Solution. These results indicate ALCON® Multi-Purpose Solution meets satisfactory levels of disinfection and preservative efficacy.

Biocompatibility:

Based on the results of the preclinical evaluations, ALCON® Multi-Purpose Solution is safe for the consumer under the recommended use conditions, as well as under conditions of reasonably foreseeable misuse.

Clinical Studies:

Two clinical studies were conducted using ALCON® Multi-Purpose Solution. The control product was Advanced Medical Optics COMPLETE® MoisturePLUS™ Multi-Purpose Solution. The safety and efficacy of the ALCON® Multi-Purpose Solution were clinically acceptable. Subjects assigned to the ALCON® Multi-Purpose Solution regimen had statistically less corneal staining compared to the control regimen with silicone hydrogel lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 2008

Alcon Research, Ltd.
c/o Kim Kracke
Assistant Director, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K071236
Trade/Device Name: Alcon Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: October 25, 2007
Received: October 26, 2007

Dear Ms. Kracke:

This letter corrects our substantially equivalent letter of December 12, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Alcon Multi-Purpose Solution

Indications For Use: For use in the daily cleaning, conditioning, rinsing, chemical (not heat) disinfection, and storage of silicone hydrogel contact lenses as recommended by your eye care practitioner.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K071236